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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/569,798

11/14/2006

Vic Young

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

12/14/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/569,798	Applicant(s) YOUNG, VIC	
	Examiner MICAH-PAUL YOUNG	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5 and 8-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5 and 8-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 9/21/10. Non-Patent Literature dated 9/21/10.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 5, and 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Cook (USPN 5,567,438 hereafter '438) in view of Nivaggioli et al (USPN 6,326,028 hereafter '028) as evidenced by Vasington et al (USPN 4,778,749 hereafter '749).

The '438 patent discloses a coating formulation comprising aqueous shellac (abstract). The coating formulation comprises shellac in a concentration from 20-30% of a coating suspension (claims). The shellac is an aqueous salt (abstract) and is applied to an appropriate substrate such as a food of pharmaceutical product via spraying (col. 5, lin. 35-42). The

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formulation further comprises a polyol plasticizer (claims), and can also comprise zein as a film additive (col. 5, lin. 45-52).

The reference is silent to the inclusion of sodium alginate, although sodium alginate is a common additive for food and pharmaceutical coating compositions. This can be seen in the '028 patent. The '028 patent discloses an alginate based coating formulation comprising at least 10% alginate (Examples). The alginate can be low viscosity and in the form of sodium alginate (col. 4, lin. 23-29). The formulation comprises a polyol plasticizer (claims) and is applied to a substrate via spraying a solution of the coating formulation (col. 3, lin. 22-32, examples).

Alginate is a common coating additive that acts as a thickening agent for coating solutions. It would have been obvious to add the sodium alginate of the '028 patent to the formulation of the '438 formulation in order to add an improved mouth-feel and stability.

Regarding the specific viscosity of the sodium alginate, the '028 patent discloses low viscosity alginates used in the coating formulation yet is silent to the specific viscosity of the compounds. Low viscosity sodium alginates are commercially available as seen in the '749 patent, where a sodium alginate solution has a viscosity of 250 cps (claims 1).

Although the '028 and '438 patents do not individually teach a coating composition comprising alginate and an aqueous shellac, both patents provides spray dried aqueous coating solutions comprising polyol plasticizers. Both coating solutions are applied to similar substrates for both food and pharmaceutical purposes and provide improved taste, and appearance to the applied substrate. As such the compounds are taught to be useful for the same purpose, within the same field of endeavor. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition

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to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

It would have been obvious to combine the prior art in order to provide an edible, stable coating formulation that improved the mouth-feel of a coated substrate. The coating would comprise a mixture of an aqueous shellac salt and sodium alginate in comparable concentrations. The '438 patent provides a coating formulation comprising 1-35% aqueous shellac salt while the '028 patent provides a sodium alginate formulation comprising at least 10% sodium alginate. Each formulation comprises a plasticizer and would improve the stability of a tablet substrate, along with improving the taste of the pharmaceutical formulation. Since both compounds are useful of the same purpose within the same field of endeavor it would have been obvious to combine the components into a third formulation for the same purpose.

Response to Arguments

Applicant's arguments filed 9/21/10 have been fully considered but they are not persuasive. Applicant argues that:

The proposed combination would not obviate the instant claims since shellac would not be known as an enteric coating polymer at the time of the invention. Thus there would be no motivation to combine the Cook patent with the Nivaggioli patent since shellac is not an enteric coating polymer.

Regarding this argument it remains the position of the Examiner that the combination of the Cook and Nivaggioli patents continue to obviate the instant claims. Regarding the alleged teaching away in the Handbook of Pharmaceutical Excipients is not an art wide ban on the

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substance as an enteric polymer, merely a comment on the dissolution as it relates to the pH of the environment. If colonic delivery is required than a substance that is insoluble in the upper gastrointestinal tract would be desirable. Shellac is soluble in higher pH values when it is combined with a polyol plasticizer. The Cook patent provides such as coating material comprising an aqueous shellac combine with a polyol plasticizer. According to the Handbook of Pharmaceutical Excipients this plasticizer would aid in the disintegration of the shellac coating. As such the Cook patent discloses a shellac coating comprising a polyol plasticizer that aids in the disintegration of the coating layer. The Nivaggioli discloses an alginate coating for similar food products. Both coating solutions are applied to similar substrates for both food and pharmaceutical purposes and provide improved taste, and appearance to the applied substrate. As such the compounds are taught to be useful for the same purpose, within the same field of endeavor. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). For these reasons the claims remain obviated.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Thursday 7:00-5:30; every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618

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